



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/807,949 | 08/09/2001 | Jan Zavada | D-0021.5C-1 | 9458 |

24988 7590 05/17/2004
LEONA L. LAUDER
465 CALIFORNIA, SUITE 450
SAN FRANCISCO, CA 94104-1840

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/807,949 | Applicant(s) ZAVADA ET AL. | |
| | Examiner Christopher H Yaen | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Zavada et al

Priority Date: 22 October 1999

1. The amendment filed 1/9/2004 is acknowledged and entered into the record. Accordingly, claims 1-30 and 43-44 are canceled without prejudice or disclaimer.
2. Claims 31-42 are pending and examined on the merits.

Sequence Listing Correction

3. Applicant's correction and submission of the corrected sequence information is acknowledged and entered into the record.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 31-42 under 35 USC 112, 1st paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that amendments to the claims to recite specific stringent hybridization conditions in view of supporting disclosure in the specification, which defines the types of molecules that specifically hybridize as those which are at least 80-90% homologous to that of SEQ ID No: 1, provides sufficient written description. Applicant further argues that because SEQ ID No: 1 has been fully disclosed, one of skill in the art would be able to fully recognize sequences which are complimentary or capable of hybridizing to SEQ ID No: 1 because routine testing can be applied to determine such sequences. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Applicant's attention is directed the Revised Interim Written

Art Unit: 1642

Description Guidelines, (specifically example 9, page 35). The example is drawn to the analysis of DNA hybridization claims wherein the specification defines a sequence by actual reduction to practice of a hybridizing sequence that has a known and specific functional activity. Because the specification defines a specific functional activity and because one of skill in the art would not predict much variability between the hybridizing sequences (due to the strict or stringent hybridization language in the claims), the written description in that case has been satisfied. In the instant case, the claims are drawn to a genus of nucleotide sequences and the specification has only defined or disclosed a single species of the broad genus claimed, namely SEQ ID No: 1. The specification fails to adequately describe a representative number of species which would satisfy the broad genus claimed, because one of skill in the art has not been taught any essential structural feature which is representative of the genus claimed. With the exception of SEQ ID No: 1, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Furthermore, although one of skill in the art would recognize a sequence which is 80-90% homologous to that of SEQ ID No: 1, the claims do not teach a readily screenable assay for which a specific function can be correlated to a specific structure.

Absent this teaching, one of skill in the art cannot determine whether the applicant was in possession of the broad genus as now claimed . Therefore, the written description rejection is maintained.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 1/9/2004.

Conclusion

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

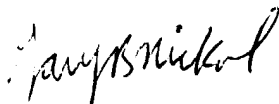
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
May 10, 2004



GARY NICKOL
PRIMARY EXAMINER